K 023413

510(k) SUMMARY

Neothermia Corporation's en-bloc Biopsy System™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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NOV 8 2002

Date Prepared: September 26, 2002

Name of Device and Name/Address of Sponsor

Common or Usual Name:	Electrosurgical Generator
Trade or Proprietary Name:	en-bloc Biopsy System™
Classification Name:	Electrosurgical Cutting & Coagulation Device & Accessories (21 C.F.R. § 878.4400) Biopsy Instrument (21 C.F.R. § 876.1075)

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Predicate Devices

Neothermia Corp.'s en-bloc Biopsy System™

Intended Use

The en-bloc Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

Technological Characteristics

The en-bloc is a percutaneous high frequency, automated, vacuum-assisted electrosurgical device used to remove tissue by automated electrosurgical cutting and

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simultaneous capture of an incised tissue volume. The Neothermia en-bloc ™ consists of a hand-held biopsy handle, upon which the single-use en-bloc Biopsy Probe is attached, with an integral cable to connect the handle to the control unit. The Probe™ contains two sets of active electrodes at its distal end – a precursor electrode and cutting/capture electrodes. The shaft of the Probe™ is encased in a stainless steel cannula. An outer plastic sleeve surrounds this stainless steel cannula and an annular gap between the sleeve and the cannula provides a conduit for vacuum-assisted removal of the gaseous products of electrosurgical cutting and any liquids (*e.g.*, blood) that may accumulate at the distal end of the Probe during the biopsy procedure. The vacuum also helps maintain the required cutting arc during automated tissue capture.

Substantial Equivalence

The modified probe has the same intended use, principles of operation, and technological characteristics as the previously cleared predicate devices. The modified device and its predicate devices are both electrosurgical devices used to biopsy breast tissue. The change does not raise new questions of safety or efficacy. The modified probe is substantially equivalent to Neothermia's cleared en-bloc probes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Neothermia Corporation
Sherrie Coval-Goldsmith
Vice President, Regulatory Affairs
One Apple Hill, Suite 316
Natick, Massachusetts 01760

Re: K023413
Trade/Device Name: en-bloc Biopsy System™
Regulation Number: 878.4400; 876.1075
Regulation Name: Electrosurgical cutting and coagulation device and accessories; Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: GEI; KNW
Dated: October 7, 2002
Received: October 11, 2002

Dear Ms. Coval-Goldsmith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023413

Device Name: en-bloc Biopsy System™

Indications for Use:

The en-bloc Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____ (Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, [illegible]ive
and Neurological De[illegible]

510(k) Number K023413

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